

Application No.: 10/666,579
Amdt dated: June 14, 2006
Reply to Office action of March 14, 2006

REMARKS/ARGUMENTS

This Amendment is filed in response to the Office action that was mailed on March 14, 2006. Claims 1-39 are pending in the Application. By this Amendment, Claims 1, 8, 11, 17-19, 21, 25 and 28-30 are amended, Claims 26 and 27 are canceled, Claims 36-39 are added, and the Specification is amended. The amendments do not introduce new matter as they are fully supported by the claims, specification, and drawings, as originally filed, or are inherent characteristics of the specification and drawings. Applicants respectfully request reconsideration and allowance of all claims in view of the above amendments and the following remarks.

Claims 1-35 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In this rejection, the Office action includes specific rejections of Claims 1, 8, and 17-25. Applicants respectfully traverse this rejection.

Claims 1 and 25 were rejected under the premise that the term "up to about" is a relative term which renders the claims indefinite. In the Office action it is indicated that the term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicants respectfully traverse this rejection because the term "up to about," as used in Claims 1 and 25, does not render the claims indefinite.

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According to MPEP § 2173.05(b), "[t]he fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. § 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). In *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. In other words, the claim was definite because the quantity "exceeding about 10% per second" could be measured. Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification." Further, when a term of degree is presented in a claim, a determination is to be made as to whether the specification provides some standard for measuring that degree. If it does not, a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention. In relation to Claims 1 and 25, there are standards for measuring the terms of degree and one of ordinary skill in the art is reasonably apprised of the scope of the invention.

Claim 1 recites a surgical access device, which includes a gel material, that facilitates insertion of a surgical instrument having a diameter up to about 37 mm through the access device. Claim 25 recites a medical device having a working channel, with a gel disposed in the working channel, that is adapted to form a seal with

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any instrument having a diameter up to about 37 mm disposed in the working channel. The term "up to about" is also used in the specification in the paragraphs beginning at: page 2, line 8; page 2, line 18; page 6, line 1; and in the Abstract of the Disclosure on page 23 of the application. First of all, the size of the instrument may be measured by a ruler, calipers, or other device for measuring the diameter of an object and one of ordinary skill in the art would know how to measure the diameter of the instrument. Next, one skilled in the art would recognize that the incorporation of a gel material may inherently permit the use of an instrument having a diameter greater than 37 mm and that, therefore, the use of the term "up to about 37 mm" covers instruments that have a diameter up to 37 mm or more. Nevertheless, applicants have amended Claims 1 and 25 and the specification (in the paragraphs beginning at: page 2, line 8; page 2, line 18; page 6, line 1; and in the Abstract of the Disclosure on page 23 of the application) by replacing the term "up to about 37 mm" with "up to 37 mm or more." These amendments do not add any new matter as support for the matter is inherent in the invention by the use of the gel material, nor do these amendments broaden the scope of the claimed invention. Based on the foregoing, Applicants respectfully submit that the rejections of Claims 1 and 25 under 35 U.S.C. § 112 are now moot and request that the rejections of Claims 1 and 25 under 35 U.S.C. § 112 be reconsidered and removed.

Claims 8 and 18 were rejected under 35 U.S.C. § 112. The Office action indicates that the use of the word "inserted" is unclear. Applicants respectfully traverse this rejection. Amended Claims 8 and 18 include a valve structure further comprising a

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cap ring which may be inserted or molded into the gel material (Claim 8) or valve structure (Claim 18). Support for the cap ring being inserted or molded into the gel material is provided in the drawings, wherein Figures 5, 6, 9 and 10 depict the cap ring 102 positioned in the gel pad 65. Support is also found in the specification in the paragraph beginning on page 11, line 12, which indicates that the gel cap 100 includes a cap ring 102, which can be inserted and molded to the pad 65a. According to Merriam-Webster's Dictionary, the term "insert" means "to put or thrust in." Based on the drawings and specification, it is clear that the cap ring may be inserted into the gel material. Based on the foregoing, Applicants respectfully request that this rejection be reconsidered and removed.

Claims 17-24 were rejected under 35 U.S.C. § 112 for reciting a "valve" and a "valve structure." The Office action indicates that there is insufficient antecedent basis for this limitation in the claim. Applicants respectfully traverse this rejection. Claim 17 was amended to replace the term "valve" with "single seal." Thus, amended Claim 17 recites: "A surgical access device ... comprising: a valve structure ...; a single seal included in the valve structure ..." (Emphasis added.) Applicants respectfully submit that Claim 17 is set up in a proper format with the valve structure and the single seal properly introduced. Therefore, the term "single seal" throughout the remainder of the claim has proper antecedent basis. Similarly, the term "valve structure" in dependent Claims 18, 19 and 21 has proper antecedent basis deriving from independent Claim 17 and it is clear what the term "valve structure" is referring to. Based on the foregoing,

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Applicants respectfully submit that this rejection is now moot and request that the rejection be reconsidered and removed.

Claim 17 was also rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,407,433 to Loomas (Loomas '433). To be anticipating, a prior art reference must disclose each and every limitation of the claimed invention, the prior art must be enabling, and the prior art reference must describe the claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339 (Fed. Cir. 2000).

The Office action indicates that Loomas '433 discloses a surgical access device including a valve structure (in Figure 1) and a valve within the valve structure (in FIG. 1, items 84, 86 and 88). The Office action further indicates that the valve of Loomas '433 has a first state having a zero seal wherein no instrument is introduced (col. 13, lines 14-17) and a second state wherein an instrument extends through and forms a seal with the valve (col. 13, lines 17-22). Applicants respectfully traverse this rejection.

Amended Claim 17 includes a surgical access device comprising a valve structure with a single seal included in the valve structure. The single seal has a first state, wherein it forms a zero seal in the absence of an instrument extending through the valve structure, and a second state, wherein it forms an instrument seal in the presence of an instrument extending through the access device. The sealing device of Loomas '433, however, includes two seals: a main gas-tight seal (18) and an auxiliary seal (10).

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The main gas-tight seal (18) of Loomas '433 includes a main sealing lip (84) that seals via an instrument passing therethrough, and an inner sealing lip (86) that forms a gas-tight seal with a spring-loaded door (88). The spring-loaded door (88), in conjunction with the inner sealing lip (86), forms a zero-seal when no instrument is inserted into the main gas-tight seal (18). (See Loomas '433 col. 13, lines 12-22.) The main sealing lip (84) of the Loomas device has an opening of a certain diameter and can form an instrument seal with instruments having a diameter equal to or larger than the diameter of the main sealing lip, but cannot form an instrument seal around instruments having a smaller diameter than the diameter of the opening of the main sealing lip.

The device of Loomas '433 includes an auxiliary seal (10) to lower the minimum end of the range of sizes of instruments for which the device may form an instrument seal. The auxiliary seal (10) includes an instrument seal (32) in which an instrument port (38) is formed. (See Loomas '433 col. 8, lines 37-42.) With the Loomas device, the minimum instrument diameter that can be accommodated depends on the diameter of the instrument port (38). (See Loomas '433 col. 9, lines 20-27.) Having an instrument port (38) that has a diameter, the instrument seal (32) of Loomas '433 cannot provide a zero-seal by itself when no instrument is inserted through the instrument port and cannot provide an instrument seal around an instrument having a smaller diameter than the diameter of the instrument port.

In contrast to the device of Loomas '433, the single seal in the valve structure of

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Applicants' Claim 17 can provide both a zero-seal by itself when no instrument is inserted therein and an instrument seal around an instrument inserted therein. Also in contrast to the device of Loomas '433, there is no requirement that an instrument be of a certain minimum diameter in order for the single seal of Claim 17 to form an instrument seal around the instrument. As stated above, the device of Loomas '433 cannot form an instrument seal around any instrument having a smaller diameter than the diameter of the instrument port (38) in the instrument seal (32) of the auxiliary seal (10). Based on the foregoing, Applicants respectfully submit that Loomas '433 fails to disclose each and every limitation of the invention claimed in Applicants' Claim 17 and that, therefore, Applicants' Claim 17 is allowable over Loomas '433.

Claim 17 was rejected again under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,865,807 to Blake, III (Blake '807). The Office action indicates that Blake '807 discloses a surgical access device including a valve structure (Figure 3) and a valve within the valve structure (Figure 3, item 36). The Office action further indicates that the valve of Blake '807 has a first state having a zero seal wherein no instrument is introduced (col. 4, lines 55-56 and 60-61) and a second state wherein an instrument extends through and forms a seal with the valve (Figure 6). Applicants respectfully traverse this rejection.

As stated above, amended Claim 17 includes a surgical access device comprising a valve structure with a single seal included in the valve structure. The single seal has a first state, wherein it forms a zero seal in the absence of an instrument

extending through the valve structure, and a second state, wherein it forms an instrument seal in the presence of an instrument extending through the access device. The sealing device of Blake '807, however, includes two seals: a primary seal (34) and a secondary seal (36). (See Blake '807 col. 4, lines 8-15.)

The primary seal (34) of Blake '807 is widely known in the art as a septum seal or septum valve and is effective at providing an instrument seal in the presence of an instrument inserted through the aperture of the seal, so long as the instrument has a larger diameter than the aperture of the seal. To provide an instrument seal, the primary seal (34) of Blake '807 includes a central aperture (34c) having a diameter less than that of an instrument passing through the trocar tube to which the primary seal is coupled. (See Blake '807 col 4, lines 38-43.) Similar to the device of Loomas '433, discussed above, by having an aperture (34c) that has a diameter, the primary seal (34) of Blake '807 cannot provide a zero-seal by itself when no instrument is inserted through the aperture and cannot provide an instrument seal around an instrument having a smaller diameter than the diameter of the aperture.

The secondary seal (36) is widely known in the art as a duckbill seal or valve and is effective at providing a zero-seal in the absence of an instrument inserted through the seal. However, it is also well known in the art that duckbill seals, without more, typically do not provide a gas-tight instrument seal when an instrument is inserted therethrough. Blake '807 fails to disclose or teach the secondary seal (36) providing an instrument seal in the presence of an instrument passing therethrough.

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To have a device that provides both a zero seal and an instrument seal, the device of Blake `807 discloses the use of both the primary (septum) seal (34) and the secondary (duckbill) seal (36). Neither the primary seal (34) nor the secondary seal (36) of Blake `807, by itself, is capable of performing both as a zero seal and an instrument seal. In contrast to the device of Blake `807, the single seal in the valve structure of Applicants' Claim 17 can provide both a zero-seal by itself when no instrument is inserted therein and an instrument seal around an instrument inserted therein. Based on the foregoing, Applicants respectfully submit that Blake `807 fails to disclose each and every limitation of the invention claimed in Applicants' Claim 17 and that, therefore, Applicants' Claim 17 is allowable over Blake `807.

Claims 1-13 and 16-35 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication No. 2004/0015185 to Ewers et al. (Ewers `185). The Office action indicates that Ewers `185 discloses a surgical access device capable of receiving a surgical instrument of about 37 mm in diameter. The Office action further indicates: that the device of Ewers `185 includes a valve having an elastomeric gel, access channel and sleeve (Figure 32, items 35 and 147); the elastomeric gel may include a silicone, urethane, urethane foam gel, elastomeric oil mixture, and vegetable oil (claims 2-7); the cap ring is molded with the gel (col. 15, lines 45-47); the sleeve is molded around the inner diameter of a cap ring (Figure 32, item 147; col. 15, lines 45-50); the device includes a support ring and wound retractor having an inner ring, outer ring, and flexible sleeve (Figure 32, items 152, 154 and 147); the sleeve can be a single

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tubular member (Figure 32, item 147); the protective sleeve and cap ring may be composed of different materials (col. 8, lines 1-3 and 42-46); that Ewers '185 further discloses a valve within a valve structure having a first and second state (Claim 12); the valve structure includes a cap ring molded with the valve, protective sleeve bonded to the cap ring, a support ring, and a wound retractor; that Ewers '185 further discloses a valve structure having an elongate configuration (Figure 32), valve wall (Figure 32), and working channel capable of accommodating a 37 mm instrument (Figure 32); that Ewers '185 further discloses an abdominal base (Figure 32, item 145); and the gel cap includes a gel pad (Figure 32, item 35s), cap ring (Figure 32, item 154), and a bonded sleeve (Figure 32, item 147). Applicants respectfully traverse this rejection.

Amended independent Claim 1 includes a "surgical access device adapted for disposition relative to an incision in a patient, the access device facilitating insertion of a surgical instrument ..., comprising: a valve structure including a gel material and an access channel; a wound retractor adapted to dilate the incision; the access channel including a protective sleeve extending into communication with the incision...."

(Emphasis added.) While Ewers '185 discloses a wound retractor (147), Ewers '185 does not separately disclose a protective sleeve extending into communication with the incision. Based on the foregoing, Applicants respectfully submit that Ewers '185 fails to disclose each and every limitation of the invention claimed in Applicants' Claim 1 and that, therefore, Applicants' Claim 1 is allowable over Ewers '185. As independent Claim 1 is allowable over Ewers '185, Applicants respectfully submit that dependent

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claims 2- 13 and 16, which depend from Claim 1, are also allowable.

Similar to independent Claim 1, amended independent Claim 17 includes a “surgical access device facilitating a sealing relationship with an instrument extending through the device and into an incision in a body wall of a patient, the access device comprising: a valve structure disposed relative to the incision in a sealing relationship with the body wall around the incision and extending into communication with the incision in the patient; a wound retractor adapted to dilate the incision; a protective sleeve extending into communication with the incision....” (Emphasis added.) While Ewers `185 discloses a valve structure disposed relative to the incision and a wound retractor (147) adapted to dilate the incision, Ewers `185 does not separately disclose a protective sleeve extending into communication with the incision. Based on the foregoing, Applicants respectfully submit that Ewers `185 fails to disclose each and every limitation of the invention claimed in Applicants’ Claim 17 and that, therefore, Applicants’ Claim 17 is allowable over Ewers `185. As independent Claim 17 is allowable over Ewers `185, Applicants respectfully submit that dependent claims 18-24, which depend from Claim 17, are also allowable.

Amended Claim 25 includes a “medical access device, including: a valve structure ...; at least one wall defining with the valve structure a working channel ...; and a gel disposed in the working channel ...; the valve structure comprising, a gel cap, and an abdominal base, and the gel cap comprising a gel pad, a circumferential cap ring, and a protective sleeve bonded or molded around an inner diameter of the cap

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ring." Ewers '185 does not disclose a protective sleeve bonded or molded around an inner diameter of the cap ring. Based on the foregoing, Applicants respectfully submit that Ewers '185 fails to disclose each and every limitation of the invention claimed in Applicants' Claim 25 and that, therefore, Applicants' Claim 25 is allowable over Ewers '185. As independent Claim 25 is allowable over Ewers '185, Applicants respectfully submit that dependent claims 28-35, which depend from Claim 25, are also allowable. Claims 26 and 27 have been canceled and Applicants respectfully submit that the rejection of Claims 26 and 27 is now moot.

Claims 1-3, 5-8, 10-12 and 25-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Loomas '433 in view of U.S. Patent No. 4,895,565 to Hillstead (Hillstead '565). The Office action indicates that Loomas '433: discloses a surgical access device having a valve structure (Figure 1) access channel (Figure 1, item 38, and protective sleeve (Figure 1, items 12 and 14); that the device is capable of receiving a surgical instrument of large diameters (col. 9, lines 20-27, 31-334, 37-49, and col. 10, lines 1-3); and teaches the ability to accommodate instruments of varying diameters by changing the diameter of the instrument port (col. 9, lines 31-34). The Office action also indicates that although Loomas '433 fails to disclose an elastomeric gel, that Hillstead '565 teaches an elastomeric gel (col. 4, lines 54-60) including a silicone (col. 3, lines 13-20) or a urethane (col. 4, lines 54-55), and that the elastomer includes a base and oil, such as silicone, creating an elastomeric oil mixture (col. 3, lines 20-27). The Office action concludes that it would have been obvious to one of

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ordinary skill in the art to modify the device of Loomas `433 by incorporating the silicone, urethane, or silicone oils in order to achieve greater lubrication and customize performance parameters of the seal (col. 3, lines 25-27; col. 4, lines 56-57). Applicants respectfully traverse this rejection.

Amended Claim 1 includes a "surgical access device adapted for disposition relative to an incision in a patient, the access device facilitating insertion of any surgical instrument having a diameter up to 37 mm or more through the access device and maintenance of a sealing relationship with said surgical instrument, comprising: a valve structure including a gel material and an access channel, the access channel being adapted to receive the surgical instrument and the gel material being adapted to form a seal with the surgical instrument disposed in the access channel; a wound retractor adapted to dilate the incision; the access channel including a protective sleeve extending into communication with the incision; and the gel material including an elastomer." Unlike Loomas `433, either by itself or in view of Hillstead `565, the gel of the present application facilitates insertion of any surgical instrument having a diameter up to 37 mm or more with maintenance of a sealing relationship with the surgical instrument. For the device of Loomas `433 to form a seal with instruments of varying diameters, it requires that the diameter of the instrument port be changed (Loomas `433 at col. 9, lines 31-34). Nothing in Loomas `433 or Hillstead `565 corrects this deficiency.

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As stated above, the Office action indicates that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Loomas `433 by incorporating the silicone, urethane, or silicone oils of Hillstead `565 to achieve greater lubrication and customize performance parameters of the seal. Applicants respectfully submit that Hillstead `565 does not disclose, teach or suggest the use of a gel as that term is described in the present application. Instead, Hillstead `565 teaches the use of oil-impregnated elastomers to form a seal (Hillstead `565 at col. 3, lines 20-27 and col. 4, lines 52-60). Those of ordinary skill in the art would not contemplate that an oil-impregnated elastomer would be equivalent to a gel material. An impregnated material typically is made by taking a material that has voids, such as porosity or other empty space, and filling those voids with a material, such as filling the voids in the material of the Hillstead `565 device with oil. Nowhere in Hillstead `565 does it teach or suggest that the oil-impregnated material can form a gel or a gel-type material.

Based on the foregoing, Applicants respectfully submit that Loomas `433, either alone or in combination with Hillstead `565, fails to disclose, teach or suggest the invention claimed in Applicants' Claim 1 and that, therefore, Applicants' Claim 1 is allowable over Loomas `433, in view of Hillstead `565. As independent Claim 1 is allowable over Loomas `433, in view of Hillstead `565, Applicants respectfully submit that dependent claims 2, 3, 5-8 and 10-12, which depend from Claim 1, are also allowable.

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Amended Claim 25 includes a "medical device, including: a valve structure ...; at least one wall defining with the valve structure a working channel sized and configured to receive a surgical instrument; and a gel disposed in the working channel and being adapted to form a seal with any instrument having a diameter up to 37 mm or more disposed in the working channel" (Emphasis added.) Applicants respectfully traverse this rejection for the reasons stated above in relation to Claim 1. As stated above, unlike Loomas `433 in view of Hillstead `565, the gel of the present application facilitates insertion of any surgical instrument having a diameter up to 37 mm or more with maintenance of a sealing relationship with the surgical instrument. For the Loomas `433 device to form a seal with instruments of varying diameters, the diameter of the instrument port must be changed (Loomas `433 at col. 9, lines 31-34). Nothing in Loomas `433 or Hillstead `565 corrects this deficiency. As stated above, Hillstead `565 teaches the use of oil-impregnated elastomers to form a seal (Hillstead `565 at col. 3, lines 20-27; col. 4, lines 52-60). Those of ordinary skill in the art would not contemplate that an oil-impregnated elastomer would be equivalent to a gel material.

Based on the foregoing, Applicants respectfully submit that Loomas `433, in view of Hillstead `565, fails to disclose, teach or suggest the invention claimed in Applicants' Claim 25 and that, therefore, Applicants' Claim 25 is allowable over Loomas `433, in view of Hillstead `565. Claim 26 has been canceled and Applicants respectfully submit that the rejection of Claim 26 is now moot.

Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) as being unpatentable

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over Loomas `433, in view of Hillstead `565, and further in view of U.S. Patent Publication No. 2004/0106942 to Taylor et al. (Taylor `942). The Office action indicates that Loomas `433 in view of Hillstead `565 fails to disclose a foam gel, but that Taylor `942 teaches an elastomer incorporating a urethane (col. 4, lines 41-45) and that the device includes a foam gel composed of a foaming agent and urethane (col. 4, lines 41-45). The Office action additionally indicates that it would be obvious to one of ordinary skill in the art at the time of the invention to modify Loomas `433 in view of Hillstead `565 by incorporation the urethane foam of Taylor `942 in order to obtain desirable mechanical and material properties. Applicants respectfully traverse this rejection.

Claims 3 and 4 depend from independent Claim 1. As stated above, Applicants submit that Claim 1 is allowable over Loomas `433 in view of Hillstead `565. Next, 35 U.S.C. § 103(c) states that "Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." Taylor `942 and the invention of the present application are both assigned to Applied Medical Resources Corporation. (For the assignment in Taylor `942, see reel number 013544, frame number 0697. For the assignment in the present application, see reel number 014536, frame number 0587.) Taylor `942 was filed on December 2, 2002 and qualifies as prior art only under 35 U.S.C. § 102(e). Therefore, under 35 U.S.C. § 103(c),

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Applicants respectfully submit that Taylor `942 cannot be cited against Applicants' present application. Based on the foregoing, Applicants respectfully submit that Loomas `433, in view of Hillstead `565, fails to disclose, teach or suggest the invention claimed in Applicants' Claims 3 and 4 and that, therefore, Applicants' Claims 3 and 4 are allowable over Loomas `433, in view of Hillstead `565.

Claims 9, 13-14, 27-31 and 35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ewers `185 or Loomas `433, in view of Hillstead `565, and further in view of U.S. Patent No. 5,803,919 to Hart et al. (Hart `919). The Office action indicates that Loomas `433 in view of Hillstead `565 fails to disclose a sleeve around the inner cap, but that Hart `919 discloses a sleeve bonded around the inner diameter of the cap ring (Figure 2, items 50 and 56; col. 4, lines 27-30). The Office action also indicates that Hart `919 teaches a plurality of axially extending sleeve members (Figure 2, items 61a-61d) having a plurality of slits (Figure 2, cuts or openings between items 61a-61d) in order to provide an improved zero closure mechanism that accounts for the fluid pressure within the incision area and reduce friction forces when inserting an instrument (col. 4, lines 32-36). The Office action concludes that it would have been obvious to one of ordinary skill in the art to modify the device of Ewers `185 or Loomas `433 in view of Hillstead `565 with the sleeve of Hart `919 in order to reduce frictional forces and improve the zero seal mechanism (col. 4, lines 32-36). The Office action also indicates: that Loomas `433 discloses that the protective sleeve is a singular tubular member (Figure 1, items 12 and 14); that Loomas `433, in view of Hillstead `565 and

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Hart '919 discloses a gel cap including a gel pad (Figure 1, item 32, cap ring (Figure 1, item 44), and sleeve bonded around an inner diameter of the cap ring; that Loomas '433 further discloses that the cap ring has an annular void located on its inner circumference capable of forming a sealing relationship with the base (Figure 3B, instep between items 32 and 50); that the base has a rounded end surface along its inner diameter capable of securing a wound retractor (Figure 3B, item 72); and that the base also includes a raised wall along its inner diameter (Figure 3B, item 72) capable of fitting a cap ring. Applicants respectfully traverse this rejection.

Ewers '185 and the invention of the present application are both assigned to Applied Medical Resources Corporation. (For the assignment in Ewers '185, see reel number 014283, frame number 0003. For the assignment in the present application, see reel number 014536, frame number 0587.) Ewers '185 was filed on September 21, 2001 and qualifies as prior art only under 35 U.S.C. § 102(e). Therefore, under 35 U.S.C. § 103(c), Applicants respectfully submit that Ewers '185 cannot be cited against Applicants' present application.

Claims 9, 13 and 14 depend from independent Claim 1, and claims 28-31 and 35 depend from independent Claim 25. Claim 27 was canceled and Applicants respectfully submit that the rejection to Claim 27 is now moot. As stated above, Applicants submit that Claims 1 and 25 are allowable over Loomas '433 in view of Hillstead '565, and Applicants further respectfully submit that Hart '919 does not correct these deficiencies. Based on the foregoing, Applicants respectfully submit that Claims

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9, 13 and 14 are allowable as depending from allowable independent Claim 1, and
Claims 28-31 and 35 are allowable as depending from allowable independent Claim 25.

Claims 15 and 16 were rejected under 35 U.S.C. § 103(s) as being unpatentable over Ewers `185 or Loomas `433, in view of Hillstead `565, in view of Hart `919, and further in view of U.S. Patent No. 4,222,126 to Boretos et al. (Boretos `126). The Office action indicates that Loomas `433 in view of Hillstead `565 and Hart `919 fail to explicitly disclose the material of the cap ring and sleeve, and that Boretos `126 discloses a cap ring (Figure 1, item 12) and sleeve (Figure 1, items 14a-14c) that may be made of the same (col. 6, lines 4-7) or different (col. 6, lines 8-11) material in order to achieve desirable material properties such as biocompatibility and strength. The Office action also indicates that Boretos `126 is considered to be analogous art because the disclosed material is reasonably pertinent to the particular problem with which Applicants are concerned: selecting a desirable material for use in fabricating the surgical access device. The Office action concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Ewers `185 or Loomas `433 in view of Hillstead `565 and Hart `919 with the material selection of Boretos `126 in order to design a biocompatible device and that it would have been an obvious matter of choice to one of ordinary skill in the art to compose the sleeve and cap ring from the same or differing materials depending upon desirable mechanical properties and economic and manufacturing constraints. Applicants respectfully traverse this rejection.

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As stated above, Ewers `185 and the invention of the present application are both assigned to Applied Medical Resources Corporation. Therefore, under 35 U.S.C. § 103(c), Applicants again respectfully submit that Ewers `185 cannot be cited against Applicants' present application.

Claims 15 and 16 depend from independent Claim 1. As stated above, Applicants submit that Claim 1 is allowable over Loomas `433 in view of Hillstead `565. Applicants further respectfully submit that neither Hart `919 nor Boretos `126, either alone or in combination, correct these deficiencies. Based on the foregoing, Applicants respectfully submit that Claims 15 and 16 are allowable as depending from allowable independent Claim 1.

Claims 31-34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Loomas `433, in view of Hillstead `565, in view of Hart `919, and further in view of U.S. Patent No. 5,628,732 to Antoon, Jr. et al. (Antoon `732). The Office action indicates that Loomas `433 in view of Hillstead `565 and Hart `919 fail to disclose a plurality of toggles or latches, but that Antoon `732 discloses a plurality of latches, notches, and mating means (Figure 3). The Office action concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Loomas `433 in view of Hillstead `565 and Hart `919 with the mating features of Antoon `732 in order to secure together the various components of a surgical access seal. Applicants respectfully traverse this rejection.

Claims 31-34 depend from independent Claim 25. As stated above, Applicants

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submit that Claim 25 is allowable over Loomas `433 in view of Hillstead `565.

Applicants further respectfully submit that neither Hart `919 nor Antoon `732, either alone or in combination, correct these deficiencies. Based on the foregoing, Applicants respectfully submit that Claims 31-34 are allowable as depending from allowable independent Claim 25.

Claims 18-24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Blake `807 in view of Hart `919. The Office action indicates that Blake `807 discloses a cap ring (Figure 3, item 2) but fails to teach the cap ring molded with the valve structure. The Office action further indicates that Hart `919 discloses a cap ring molded to the valve structure (col. 4, lines 23-32) and a sleeve bonded around the inner diameter of the cap ring (Figure 2, items 50 and 56; col. 4, lines 27-30). The Office action also indicates that Hart `919 teaches a plurality of axially extending sleeve members (Figure 2, items 61a-61d) having a plurality of slits (Figure 2, cuts or openings between items 61a-61d) in order to provide an improved zero closure mechanism that accounts for the fluid pressure within the incision area and reduce friction forces when inserting an instrument (col. 4, lines 32-36). The Office action concludes that it would have been obvious to one of ordinary skill in the art to modify the device of Blake `807 with the sleeve of Hart `919 in order to reduce frictional forces and improve the zero seal mechanism (col. 4, lines 32-36). The Office action also indicates: that Blake `807 teaches a support ring circumferentially located around the valve (Figure 3, item 36a) and a wound retractor located within (Figure 3, item 36); that the wound retractor

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includes an inner ring (Figure 3, item 36a), outer ring (Figure 3, item 36b), and flexible sleeve (col. 4, lines 48-50); and that Blake `807 discloses a single tubular sleeve that provides wound protection (Figure 3, item 38). Applicants respectfully traverse this rejection.

Claims 18-24 depend from independent Claim 17. As stated above, Applicants submit that Claim 17 is allowable over Blake `807. Applicants further respectfully submit that Hart `919 does not correct this deficiency. Based on the foregoing, Applicants respectfully submit that Claims 18-24 are allowable as depending from allowable independent Claim 17.

Claims 1-35 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of Ewers `185 (co-pending U.S. Application No. 10/381,220) in view of Blake `807 and Antoon `732. The Office action indicates that although the conflicting claims are not identical, they are not patentably distinct from each other because as to claims 1 and 25, Ewers `185 discloses in Claim 1 and 20 a valve structure including a gel, elastomer, and access channel, but fails to explicitly disclose a sleeve and a channel capable of accommodating an instrument 37 mm in diameter. The Office action further indicates that Blake `807 discloses a sleeve (col. 5, lines 10-13). The Office action concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ewers `185 in view of Blake `807 in order to act as an instrument guide (col. 5, lines 10-13). The Office action also indicates that Ewers `185, in view of

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Blake `807, fails to explicitly disclose accommodating an instrument of 37 mm in diameter, but that it would have been an obvious matter of choice to one of ordinary skill in the art to design the valve to accommodate instruments of 37 mm in diameter in order to enable surgeons to utilize larger or multiple instruments. Regarding Claims 8, 9, 18, 19, 26, and 27, the Office action indicates that it is an obvious matter of choice to one of ordinary skill in the art to arrange the location and relative orientation of the components of a valve structure. Regarding Claims 10-12, 21 and 22, the Office action indicates that Blake `807 discloses a wound retractor as a means of creating an additional seal in the surgical access valve. Regarding Claims 13-16, 20-24, 28 and 29, the Office action indicates that it is an obvious matter of choice to one of ordinary skill in the art to arrange the features and material composition of the sleeve so as to enhance the zero seal and ability to guide inserted instruments. Regarding Claim 17, the Office action indicates that Ewers `185 discloses the limitations of Claim 7 in Claim 12. Regarding Claims 31-35, the Office action indicates that Ewers `185, in view of Antoon `732, discloses a number of mating features between the base and cap ring and concludes that it would have been obvious to one of ordinary skill in the art to modify Ewers `185 with Antoon `732 in order to secure together the components of the valve structure. The obviousness-type double patenting rejection was made provisional because the conflicting claims have not in fact been patented.

As stated above, Applicants respectfully submit independent Claims 1, 17 and 25 are allowable over Ewers `185. Applicants also respectfully submit that Blake `807

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and Antoon '732, either alone or in combination, do nothing to correct the deficiencies. Further, Applicants respectfully submit that dependent Claims 2-16, 18-24, and 28-35, which depend from independent Claims 1, 17 and 25, respectively, are also allowable over Ewers '185 in view of Blake '807 and Antoon '732. Applicants respectfully forego filing a Terminal Disclaimer in compliance with 37 C.F.R. §§ 1.321(c) or 1.321(d) at this time and choose instead to wait until it is known which claims will proceed to issuance in this case and which form they will be allowed in.

Applicants respectfully request that a timely Notice of Allowance be issued in this case. If the Examiner believes that a telephone conference with Applicants' attorney might expedite prosecution of the Application, the Examiner is invited to call at the telephone number indicated below.

Sincerely

APPLIED MEDICAL RESOURCES

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